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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,209	03/01/2004	Soonkap Hahn	81671	3988

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FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,209	HAHN, SOONKAP	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14* is/are allowed.

6)☒ Claim(s) *1,3,5-12,15,17,22 and 25* is/are rejected.

7)☒ Claim(s) *2,4,13,16,23 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Claim Status

Claims 1-17 and 22-25 are pending.

Claims 18-21 are cancelled.

Claims 1-17 and 22-25 are being examined.

Applicants' arguments to the objections/rejections stated in the previous office action have been fully considered and are persuasive in part. Rejections not reiterated hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 3, 5-12, 15, 17, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (Korean IPO Pub. No. 10-2000-0072201 Pub.Date 17 August 2000), in view of Beattie et al (US PAT 6,268,147).

The claims are drawn to a method of detecting mutations that are indicative of Fragile X syndrome by testing obtained genomic DNA using labeled oligonucleotides to determine the number of CGG repeats in the obtained genomic DNA.

Kim teach a method of diagnosing Fragile-X syndrome by using DNA Probes to identify the number of CGG repeats in the obtained genomic DNA. Specifically, Kim teaches obtaining a genomic DNA sample (para. 16). Kim teaches the generation of single stranded DNA (para. 18, line 6). Kim teaches the hybridization of two differentially labeled probes to targets within the denatured each probe directed to a different genomic region of FMR1 gene; one probe being targeted to STR's CGG or GCC and one probe being targeted to a region of FMR1 gene (para. 48, line 6). Kim teach the immobilization of the labeled target to a solid support (para.18, line 6), separating the hybridized DNA from non-hybridized nucleic acids. Kim teaches measuring the colorimetric intensities of the the CY3 and CY5 fluorescent dyes that label the different probes and determining a ratio between cy3 and cy5 then compared to a known control to determine the number of CGG or GCC STR repeats (para. 49). The differences between the method steps of the art are minor and being viewed similarly as the steps in a product by process claim.

Although Kim does not employ PCR directly in the method of identifying the number of STR's in FMR1, Kim teaches that the application of PCR to amplify DNA fragments of the region of the FMR1 gene surrounding the CGG STRs is also employed in the analysis of Fragile-X syndrome.

Kim does not teach using microarray technology to capture the differentially labeled hybridized target STRP's. The biotin/streptavidin method of capturing nucleic acid taught in Kim is an alternate method of capture of the hybridized nucleic acid and it results in the capture of the hybridized nucleic acid the same way as any other method of capturing, such as e.g. in a microarray. Various alternative methods of capturing nucleic acids of interest are well known in the art, in particular Beattie et al teach that there exist many alternative immobilization methods that have been described in the prior art that are equivalent (col. 30, lines 2-14) to capture nucleic acids. For example, Beattie et al teach the using microarray technology to the capture nucleic acids (abstract, col. 37-38). The formation of single stranded DNA, hybridization with labeled probes, and subsequent capture by an oligonucleotide probe immobilized on a microarray is analogous to the method of Kim.

It would have been obvious to one of skill in the art to use any of the known functionally equivalent methods of capturing nucleic acids. For example, one could use a microarray capturing method such as the method taught by Beattie et al and had a reasonable expectation of being equally successful.

One would have been motivated to do so because Beattie et al teach oligonucleotide hybridization is a rapid and sensitive method for simultaneously analyzing large numbers of mutations.

Response to arguments

Applicant argues that the invention is distinguished over Beattie et al because the applicants method employ the reading of 2 colorimetric intensities and determining a

ratio. The argument is found not persuasive because Beattie teaches the method has the advantage of providing a convenient means for introducing one or more labels into a target (col. 8, line 64 to col. 9, line 16) and comparing (reading on ratio) the hybridization labeled probes to identify mutations (col 62, line 22-29).

Beattie is being applied currently to demonstrate the capture of labeled nucleic acid.

Allowable Subject Matter

Claim 14 is allowable. After a diligent search or the art, it is found that the prior art does not fairly teach the formula, N=30+(A-1.03)66.4, used to calculate the number of CGG repeats in FRAXA/5' untranslated FMR1 region.

Claims 2, 4, 13, 16 and 23-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1, 3, 5-12, 15, 17, 22, and 25 are rejected.

Claims 2, 4, 13, 16, 23 and 24 are objected to.

Claim 14 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is

(571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/

MICHAEL BORIN, PH.D
PRIMARY EXAMINER